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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/676,176	10/01/2003	Fredrik Solhage	ANO 6277 US/3166	6797	
7590 12/28/2006 Michelle J. Burke Akzo Nobel Inc Intellectual Property			EXAM	EXAMINER	
			ISSAC,	ISSAC, ROY P	
7 Livingstone Avenue Dobbs Ferry, NY 10522		× .	ART UNIT	PAPER NUMBER	
_ 5505 1 511,7,5			1623		
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SHORTENED STATUTOR	Y PERIOD OF RESPONSE	MAIL DATE	DELIVER	DELIVERY MODE	
3 MO	NTHS	12/28/2006	PAI	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary    10/676,176   SOLHAGE ET AL.					
Roy P. Issac 1623					
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).					
Status					
1) Responsive to communication(s) filed on 08 November 2006.					
2a) This action is <b>FINAL</b> . 2b) This action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims					
4)⊠ Claim(s) <u>1-28</u> is/are pending in the application.					
4a) Of the above claim(s) is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.					
6)⊠ Claim(s) 1-28 is/are rejected.					
7) Claim(s) is/are objected to.					
8) Claim(s) are subject to restriction and/or election requirement.					
Application Papers					
9) The specification is objected to by the Examiner.					
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.					
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).					
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.					
Priority under 35 U.S.C. § 119					
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:					
1. Certified copies of the priority documents have been received.					
2. Certified copies of the priority documents have been received in Application No					
3. Copies of the certified copies of the priority documents have been received in this National Stage					
application from the International Bureau (PCT Rule 17.2(a)).					
* See the attached detailed Office action for a list of the certified copies not received.					
Attachment(s)					
1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  Paper No(s)/Mail Date					
3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 1/02/2004.  5) Notice of Informal Patent Application 6) Other:					

Art Unit: 1623

### **DETAILED ACTION**

This application claims priority under 35 U.S.C § 119(e) from the provisional application 60/415,184 filed 10/01/2002.

#### Election/Restrictions

Applicant's election without traverse of species of claimed in claim 9 in the reply filed on 08 November 20056 is acknowledged. However, in further consideration the requirement for Election/Restrictions is withdrawn. Claims 1-28 are currently pending and are examined on the merits herein.

## Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for substituents –CH<sub>2</sub>-CH(OH)-CH<sub>2</sub>-N<sup>+</sup>((CH<sub>3</sub>))<sub>2</sub>)CH<sub>2</sub>C<sub>6</sub>H<sub>5</sub> Cl-, and –CH<sub>2</sub>-CH(OH)-CH2-N<sup>+</sup>((CH<sub>3</sub>)<sub>3</sub>)Cl-, does not reasonably provide enablement for **any** aromatic or **any** non-aromatic substituents. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Art Unit: 1623

The instant specification <u>fails</u> to provide information that would allow the skilled artisan to practice the instant invention. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

## Nature of the invention:

The instant application relates the cationization of polysaccharides with two quaternary amine substituents, one with an aromatic group and another without an aromatic group.

### The relative skill of those in the art:

The relative skill of those in the art is high, with a typical practitioner having obtained a PhD, M.S. or equivalent advanced degree.

### The breadth of the claims:

The instant claims are deemed very broad because they encompass any of the millions of substituents that can be considered either aromatic or non-aromatic.

Claims where aromatic group is describes as "group containing 1 to 12 carbon

Art Unit: 1623

atoms" encompass thousands of permutations of which only one is exemplified in the instant application.

The amount of direction or guidance presented and the presence or absence of working examples:

The instant application exemplifies polysaccharides cationised with two substitutents, the aromatic substituent –CH<sub>2</sub>-CH(OH)-CH<sub>2</sub>-N<sup>+</sup>((CH<sub>3</sub>))<sub>2</sub>)CH<sub>2</sub>C<sub>6</sub>H<sub>5</sub>, and the non-aromatic substituent –CH<sub>2</sub>-CH(OH)-CH2-N<sup>+</sup>((CH<sub>3</sub>)<sub>3</sub>)CI-. The specification further describes varying degrees of substitution of the two groups. However, no other substituent is exemplified. The term aromatic encompass a wide range of compounds with diverse properties, including varying reactivity, solubility and functionality. The operability of one particular aromatic substituent does not predict the operability of all other aromatic substituents. Similarly, the term non-aromatic group is also a description that encompasses a wide variety of groups with varying properties. Some examples of non-aromatic substituents include carbohydrates, lipids and long chain alkyl polymers, all of which have divergent chemical and physical properties. As such, one of skill in the art would not expect any substituents other than ones with strong structural similarity to the ones exemplified to function similarly.

"Aromatic implies various features, properties, or behaviors to chemists with different backgrounds." (Schleyer PV. Chemical Reviews, 2001, 1115-1117, Page 1117, Column 2, Paragraph 3). The term aromatic despite its use in the literature is nonreductive. "They have no precise meaning and do not denote

Art Unit: 1623

directly mreasurable quantities." (Page 1115, Column 1, Paragraph 3). They encompass large groups of compounds that often have dissimilar properties. For example, there are nonbenzenoid aromatics. Some of the compounds are negatively charged. (Page 1115, Column 2, paragraph 2). Some are heterocyclic while others are transition metal complexes. Different physical properties do not necessarily correlate with aromaticity criteria. (Page 1116, Column 2, Paragraph 3). Some of the heterocyclic complex are difficult to evaluate. (Page 1117, Column 1, Paragraph 1). In view of the complexity and breadth of "aromatic" compounds, the applicant have not enabled one of skill in the art to practice the invention in the full scope of the claims herein.

The lack of working examples is a critical and crucial factor to be considered, especially in cases involving an unpredicatable and undeveloped art.

See MPEP § 2164.

The predictability or lack thereof in the art and the quantity of experimentation necessary:

Organic synthesis in particular is a very unpredictable art. Some of the synthesis efforts in organic chemistry take years to complete, often an exercise in trial and error. The generic claims in the instant application encompass thousands of compounds with wide varying functional groups. The additional groups claimed by the generic formula have well-established divergent function and properties.

Art Unit: 1623

Thus, the specification fails to provide <u>clear and convincing</u> evidence in <u>sufficient</u> support of the claimed compounds in their full scope described by the terms "aromatic group" and "non-aromatic" group.

Genentech, 108 F.3d at 1366, sates that, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion." And "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the <u>Wands</u> factors as discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in <u>undue experimentation</u> to practice the invention commensurate in scope with the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8, 10-17 and 19028 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitations "substituent having an aromatic group" and a "substituent having no aromatic group" renders the claim indefinite. The recited phrases do not convey a structural formula or chemical name to one of ordinary skill in the art. In the

Art Unit: 1623

absence of a structural formula or chemical name, the claims reading on "substituent having an aromatic group" and "substituent having no aromatic group" wherein each variables are not distinctly claimed are indefinite as one of skill in the art would not be apprised of the metes and bounds of claimed invention.

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6, 8, 12, 15-17, 19-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Matsunaga Y et.al. (JP 62149702, English Translation; PTO-1449, Included by the applicant).

Matsunaga et. al. discloses 3-chloro-2-hydroxypropyl trimethylammonium chloride (CMT) adduct of polysaccharide that further contains varying ranges of benzyl adduct. (Page 9, Table 1). Note that the 3-chloro-2-hydroxypropyl trimethylammonium chloride is the same non-aromatic substituent exemplified in the instant application. The polysaccharide from corn starch has a 2:1 ration of non-aromatic to aromatic substituent, while for tapioca, the ratio is 5:4, and for potato it is 3:4.7. (Table 1). Matsunaga discloses 6.5-10% substitution of CTA and 3-5% substitution of the aromatic group, benzyl chloride. The degree of

Art Unit: 1623

cationization ranged from 3.9% to 6.0%. (Table 1). These ranges fall within the claimed ranges herein. Matsunaga further discloses a criteria for selecting substituents to prevent resolidification in paper manufacturing. (Page 2-3). The criteria includes the selection of a group with a high molecular weight and bulky structure, high boiling point. Matsunaga et. al. elects the benzyl as a group that meets this criteria in making benzyl substituted polysaccharides. (Page 4, lines 18-25). Benzyl chloride was added with CTA simultaneously to polysaccharide containing solution to get polysaccharides substituted with both groups. Even though Matsunaga does not report the charge density of the composition, it is expected to have the same charge density as the instant application because the compositions' substitution range falls within the instant application.

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 5, 7, 9-11, 13-14, 18 and 24-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsunaga et. al. (JP 62149702, English Translation; PTO-1449, Included by the applicant), in view of Persson et. al. (WO 99/55964; PTO-1449, Included by the applicant).

Art Unit: 1623

The disclosure of Matsunaga et. al. is discussed above in the 102 rejection.

Matsunaga et. al. does not expressly disclose the use of the particular aromatic quaternary amine substituent of the general structure I of the instant application. Matsunaga et. al. does not disclose substitutents wherein R1, R2 and R3 together with N form an aromatic group containing 5-12 carbon atoms.

Persson et. al. discloses cationised polysaccaharides with quaternary ammonium substituents. The cationized polysaccharides have the following structure, as disclosed in the instant application including the particular substituents exemplified in the instant application. (Page 4, lines 3-25).

$$\begin{array}{c|c}
R_1 & (1) \\
 & X^* \\
P - (-A - N^{\dagger} - R_2)_n \\
 & R_3
\end{array}$$

Persson et. al. discloses 2-hydroxypropyl dimethyl benzyl ammonium chloride as one of the hydrophobic substituents for polysaccharides. (Example 1, Page 11, lines 20-30). Persson et. al. discloses substituents where R1, R2 and R3 together with N form an aromatic group containing 5-12 carbon atoms. Presson et. al. discloses two polysaccharide polymers each individually has the particular substituents of the instant application. (Page 11, Example 1, compounds P1 and Ref 1). Persson et. al. further discloses epichlorohydrin as a suitable modifying agent.

Art Unit: 1623

It would have been obvious to one of ordinary skill in the art at the time the invention was made to synthesize a polysaccharide with a first substituent comprising –CH2-CH(OH)-CH2-N<sup>+</sup>((CH3)2)CH2C6H5 CI- and the second substituent -CH2-CH(OH)-CH2-N<sup>+</sup>((CH3)3)CI-, because Matsunaga et. al. discloses a polysaccharide with two types of substituents, one aromatic and one non-aromatic as claimed herein, and Persson et. al. discloses the particular aromatic substituent –CH2-CH(OH)-CH2-N<sup>+</sup>((CH3)2)CH2C6H5 CI- for polysaccharides. Note that, independent claims 21 and 25 are in the product-by-process format. These two claims appear to give rise to the same products claimed in claims 1-20.

One of ordinary skill in the art would have been motivated to use the particular substituents of the instant application because Matsunaga et. al. discloses polysaccharides with two types of substituents, one particular substituent (non-aromatic) identical to the instant application, and the other structurally similar to the one claimed herein, well known for use as substituent in polysaccharide paper production by Persson et. al. If the claimed invention and the structurally similar prior art species share any useful property, that will generally be sufficient to motivate an artisan of ordinary skill to make the claimed species. It is a reasonable expectation that similar species usually have similar properties. See Dillon, 919 F.2d at 693, 696, 16 USPQ2d at 1901, 1904. See also, Deuel, 51 F.3d at 1558, 34 USPQ2d at 1214. In fact, similar properties may formally be presumed when compounds are very close in structure. Dillon 919 F.2d at 693, 696, 16 USPQ2d at 1901, 1904, as noted in MPEP 2144.

Art Unit: 1623

One of ordinary skill in the art would have reasonably expected that the substitution of –CH2-CH(OH)-CH2-N<sup>+</sup>((CH3)2)CH2C6H5 CI- instead of benzyl chloride would have resulted in polysaccharide with beneficial properties in paper production.

As such, the invention is prima facie obvious over the combined teachings of the prior art.

No Claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy P. Issac whose telephone number is 571-272-2674. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1623

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Roy P. Issac Patent Examiner Art Unit 1623 S. Anna Jiang, Ph.D.

Supervisory Patent Examiner

Art Unit 1623